510(k) Summary

OCT 3 1 2012

Cayenne Medical, Inc.

Quattro™ Link Knotless Anchor

ADMINISTRATIVE INFORMATION

510(k) Number	**K122314**
Manufacturer Name:	Cayenne Medical, Inc. 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Telephone (480) 502-3661 FAX (888) 334-4079
Official Contact:	Kereshmeh Shahriari 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 kshahriari@cayennemedical.com Telephone (480) 502-3661 FAX (888) 334-4079
510(k) Summary Preparation Date	July 31, 2012

DEVICE NAME

Product Code	MBI
Classification Names:	Fastener, Fixation, Nondegradable, Soft Tissue
Trade/Proprietary Name:	Quattro™ Link Knotless Anchor
Common Name:	Suture Anchor

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code is MBI, Fastener, Fixation, Nondegradable, Soft Tissue. These devices are reviewed by the Orthopedic Joint Devices Branch.

INTENDED USE

The Cayenne Medical, Inc. Quattro Link Knotless Anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder
- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Bicep tenodesis

Elbow, Wrist, and Hand
- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair

Knee
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medials obliquous advancement
- Illiotibial band tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or Lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

DEVICE DESCRIPTION

The Quattro™ Link Knotless Anchor is a sterile, manually operated, single procedure suture anchor device for reattachment of soft tissue to bone in shoulder, elbow, wrist, hand, knee, foot, and ankle procedures. The anchor is mounted on an inserter. The Quattro Link Knotless

Anchor incorporates design features that facilitate suture anchor placement under arthroscopic or open, limited access conditions in soft tissue to bone reattachment procedures. The anchor is offered in two different configurations, with or without a self-punching (SP) metal tip (PEEK anchor body and titanium alloy tip and PEEK only). The all PEEK anchor is offered in three different sizes, 2.9mm, 4.5mm and 5.5mm. The PEEK and titanium alloy tip anchor is offered in one size, 4.5mm.

NON-CLINICAL TESTING

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included. Mechanical testing was performed on the Quattro Link Knotless Anchor and Inserter. It was shown that maximum suture slip force (ultimate pull-out strength) is significantly higher than that of the predicate devices. Dimensional analysis was performed on the Quattro Link Knotless Anchor and Inserter. Product dimensional analysis met the components and product specifications.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Quattro Link Knotless Anchor is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices: Cayenne Medical Quattro Link (CuffLink) Knotless Anchor (K112876), Smith & Nephew FOOTPRINT Ultra PK Suture Anchor (K093897) and Smith & Nephew Bioraptor Suture Anchor (K093428). The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

The subject device Quattro Link Knotless Anchor with Inserter has the same intended use, materials, manufacturing processes, packaging, sterilization method, and shelf life as the Cayenne Medical Quattro Link (CuffLink) Knotless Anchor (K112876). The subject device Quattro Link Knotless Anchor with Inserter has identical design and technology to the Cayenne Medical Quattro Link (CuffLink) Knotless Anchor (K112876). Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 31 2012

Cayenne Medical, Incorporated
% Ms. Keresheh Shahriari
16597 N. 92nd Street, Suite 101
Senior Director Regulatory Affairs and Quality Assurance
Scottsdale, Arizona 85260

Re: K122314
Trade/Device Name: Quattro™ Link Knotless Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 16, 2012
Received: October 18, 2012

Dear Ms. Shahriari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122314

Device Name: Quattro™ Link Knotless Anchor

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122314